Review of Prescription Drug Monitoring Programs in the United States

Kentucky All Schedule Prescription Electronic Reporting Program (KASPER)
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Introduction

Prescription drug monitoring programs (PDMPs) collect prescription data on medications classified as federal controlled substances. The information is stored in a central database and can be accessed by authorized users. Although programmatic details differ among states, in general, all PDMPs are designed to assist in detecting and preventing abuse, misuse, and diversion of controlled substances. Specifically, programs are targeted toward reducing the incidence of 'doctor shopping' which occurs when patients see multiple providers and pharmacies with the intent of obtaining controlled substances for misuse and/or diversion (1).

Health care professionals who prescribe or dispense controlled substances can access PDMP databases with increasing ease and efficiency. Since the advent of electronic prescription drug monitoring systems, access can occur at the point of care and can assist prescribers and dispensers in making treatment decisions. Patients' reported use of scheduled medications can be confirmed by accessing PDMP reports, allowing prescribers and dispensers to detect individuals who may be feigning illnesses in an effort to acquire drugs for the purpose of abuse or diversion. The term prescriber as used in this report includes physicians, dentists, nurse practitioners and other health care professionals authorized to prescribe controlled substances; the term dispenser refers to those individuals who dispense controlled substances, the vast majority of whom are community pharmacists.

In addition to prescribers and dispensers, most states allow regulatory and law enforcement agencies involved in drug-related investigations to access PDMP databases, enabling them to more efficiently collect and analyze data that may be useful in identifying those individuals involved in illegal trafficking or misuse of prescription drugs.

Origin and Funding of Prescription Drug Monitoring Programs

Since the early 1930's, state regulatory, administrative, and law enforcement agencies have seen the need for and have worked to establish systems to track and monitor the prescribing and dispensing of particular prescription drugs. California was the first state to establish a PDMP in 1939. By 1992, 10 states had operational PDMPs and many more states were in the process of enacting legislation for the establishment of a PDMP. Although the common goal among these early programs was to reduce prescription drug abuse and diversion, there was wide variation in program design, objectives, and operation. In 2002, as part of an effort to standardize and unify PDMPs, the National Alliance for Model State Drug Laws (NAMSDL) drafted a model program, outlining common goals that should be shared among existing and future PDMPs. These goals include: 1) detection and prevention of scheduled prescription drug abuse and misuse; 2) support of access to controlled substances for legitimate medical use; 3) facilitation of the identification and provision of treatment to persons who may be addicted to scheduled prescription drugs; 4) utilization of controlled substances use and abuse

trend data to inform public health and public policy initiatives; and 5) education of individuals about PDMPs, and the use, abuse, and diversion of scheduled prescription drugs (2).

With the increasing usage of PDMPs and the steady increase in the abuse and diversion of controlled substances, the Bureau of Justice Assistance (BJA), Office of Justice Programs in the U.S. Department of Justice created the Harold Rogers Prescription Drug Monitoring Program (HRPDMP) in 2002 (3). Funds for this program were provided by Congress to assist in the planning, implementation, and in some cases the enhancement of state PDMPs. From 2002 to 2008, over 100 state HRPDMP grants were awarded by the BJA. For fiscal year (FY) 2009, $7 million was appropriated by Congress for the HRPDMP. President Barack Obama proposed that the budget for 2010 would include $7 million for the grant program (4).

A second source of funding for PDMPs is the National All Schedules Prescription Electronic Reporting Act (NASPER) administered by the U.S. Department of Health and Human Services. This program also is designed to assist states in creating a PDMP or enhancing an existing one; however, it differs from the HRPDMP in that it does not provide funding for planning a PDMP (5). During fiscal year (FY) 2009, $2 million was appropriated by Congress for NASPER implementation. Grants were first made available in FY 2009 and an additional $2 million was proposed by President Obama for NASPER in the FY 2010 budget (5)**.**

Recommended Components of Prescription Drug Monitoring Programs

According to the National Alliance for Model State Drug Laws (NAMSDL), there are seven key characteristics of a strong PDMP (6).

1. Drugs being monitored should include federal controlled substances and drugs that have been identified by law enforcement agencies and addiction specialists to have abusive potential. It is also suggested that some substances, not classified as scheduled, should be monitored if found to be highly abused, and state legislation should be passed to place these substances in a schedule.
2. Monitoring systems should proactively provide information to law enforcement agencies, licensing officials, and other appropriate individuals. This information should be reviewed by a drug monitoring official and if there is reason to suspect that a violation has occurred, the offender should be reported to the appropriate agency. In addition, a statute must be in place that allows programs to disclose information for public research, policy, and educational purposes, provided that no personal identifiers are included.
3. Persons authorized to request information from the program should include dispensers, prescribers, law enforcement agencies, and licensing officials.
4. Authorized users of the program should receive special training which would ensure proper use of the information obtained from the program.

5. Programs should include an evaluation component aimed at identifying cost-benefits and assessing ways to improve the existing program.
6. Data collected through PDMPs should not be subject to public or open records laws. Penalties should be instituted for individuals who either knowingly disclose or use the information in ways not authorized by the law.
7. Each state should have measures in place to address interstate misuse and abuse of prescription drugs.

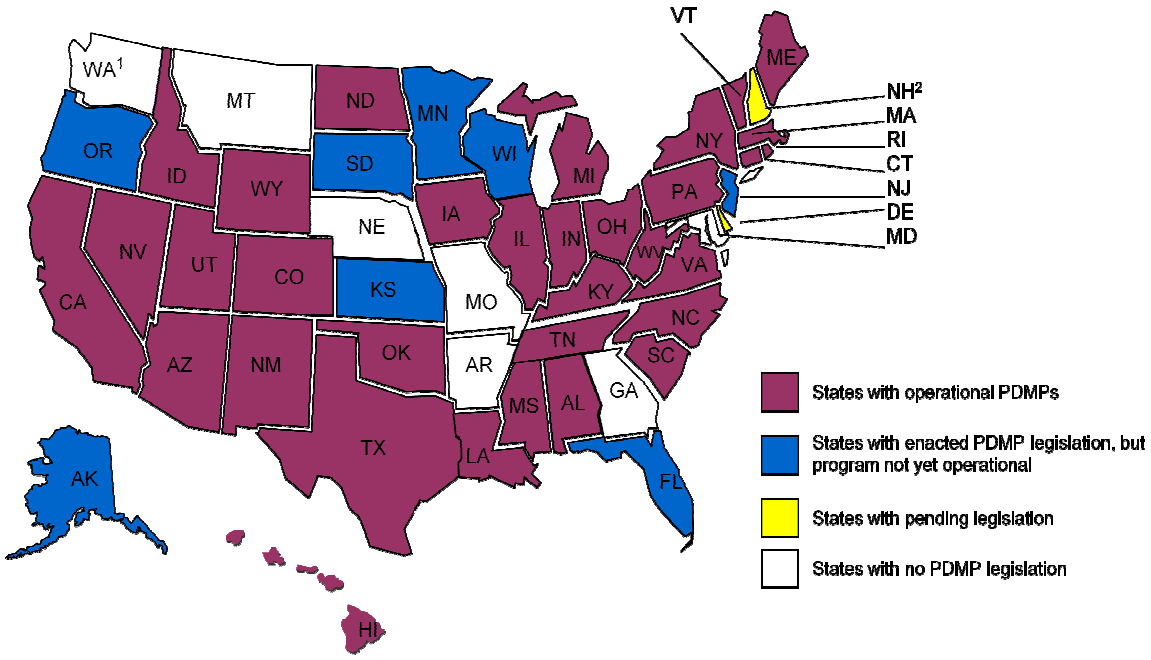
Current Status of Prescription Drug Monitoring Programs

As of June 1st, 2010, 42 states had laws authorizing the establishment of a PDMP, 33 of which are currently in operation (Figure 1) (2). Eight states - Alaska, Florida, Kansas, Minnesota, New Jersey, Oregon, South Dakota and Wisconsin - have legislation in place for the establishment of a PDMP; however, these systems are not yet operational.

In 2007, legislation was enacted in the state of Washington for the establishment of a PDMP, housed in the Department of Health. In 2008, initial funding for program implementation was provided by the state legislature; however, Washington state officials report that recurring funding to cover the cost of program operation was not forthcoming so the program was never fully implemented and has recently been suspended (8).

Two states - New Hampshire and Delaware - have legislation pending for the establishment of a PDMP (2).

Figure 1. States with Prescription Drug Monitoring Programs



[1]Washington has temporarily suspended its PMP operations due to budgetary constraints. A bill was proposed during the most recent legislative session that would have allowed for the statewide operation of a privately funded PMP; however, the bill did not pass, and the Washington Legislature is no longer in session. [2]The proposed New Hampshire PMP bill failed to pass a committee vote and is unlikely to become law this session.

Characteristics of Existing Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs are housed in and operated by different governmental agencies. Most commonly, programs are operated by state boards of pharmacy (14 of 33). State Health Departments, including Departments of Public Health and Departments of Health and Human Services, oversee PDMPs in 11 states. Law enforcement agencies, professional licensing boards other than pharmacy, and consumer protection agencies also oversee PDMPs. Differences also exist regarding the schedules monitored by the PDMP. Table 1 summarizes the characteristics of current PDMPs in operation, including the schedules of drugs being monitored, year of legislation enactment, date that data collection started, and the responsible agency (9 - 11).

Table 1. Prescription Drug Monitoring Program Characteristics by State

State	Agency governing program	Schedules monitored	Year enacted	Date data collection started
Alabama	Department of Public Health	II-V	2004	April 2006
Alaska*	Division of Corporations, Business and Professional Licensing	II-V	2008	2011 (tentative)
Arizona	Board of Pharmacy	II-IV	2007	October 2008
California	Department of Justice, Bureau of Narcotic Enforcement	II-IV	1939	1939 triplicate prescription program, Electronic monitoring implemented in 1997
Colorado	Department of Regulatory Agencies-Board of Pharmacy	II-V	2005	July 2007 data collection; 2008 users now allowed to request prescription information
Connecticut	Department of Consumer Protection	II-V	2007	July 2008
Florida*	Office of Drug Control	II-IV	2009	Goal is December 2010
Hawaii	Department of Public Safety-Narcotics Enforcement Division	II-V	1943	1992 schedule II only; July 1999 II-IV
Idaho	Board of Pharmacy	II-IV	1967	1967 triplicate prescription program; October 1997
Illinois	Department of Health and Human Services	II-V	1958	1958 start of prescription data collection; 1968 triplicate prescription program; April 1st 2000 electronic monitoring of schedule II only; January 2008 expansion to include II-V
Indiana	Board of Pharmacy	II-V	1994	1994 schedule II only; July 2005 expanded to schedules II-V
Iowa	State Board of Pharmacy Examiners	II-IV	2006	January 2009
Kansas *	Board of Pharmacy	II-IV	2008	Goal is October 2010
Kentucky	Cabinet for Health and Family Services, Office of Inspector General	II-V	1998	January 1999
Louisiana	Board of Pharmacy	II-V	2006	November 2008
Maine	Office of Substance Abuse	II-IV	2003	July 2004
Massachusetts	Department of Public Health	II	1992	1994
Michigan	Bureau of Health Professions	II-V	1988	1989 schedule II only; January 2003 schedule II-V
Minnesota *	Board of Pharmacy	II-IV	2007	Goal is 2010
Mississippi	Board of Pharmacy	II-V	2005	April 2005
Nevada**	Board of Pharmacy	II-IV	1995	January 1st 1997
New Jersey*	Division of Consumer Affairs	II-IV	2008	
New Mexico	Board of Pharmacy	II-IV	2004	July 2005
New York	Department of Health-Bureau of Narcotic Enforcement	II-V	1972	July 1982
North Carolina	Department of Health and Human Services	II-V	2005	July 2007
North Dakota	Board of Pharmacy	II-V	2005	September 2007; Pharmacists were asked to provide data from January 2007
Ohio	Board of Pharmacy	II-V	2005	May 2006
Oklahoma	Bureau of Narcotics	II-V	1990	1991 schedule II only; July 2006 electronic

Oregon*	Department of Health and Human Services	II-IV	2009	2010 (tentative)
Pennsylvania	Office of the Attorney General	II	1972	Original circa 1973; Current data use 2002
Rhode Island	Department of Health, Board of Pharmacy	II- III	1978	1979 triplicate prescription program-schedule II; July 1997 electronic monitoring of schedules II-III
South Carolina	Department of Health and Environmental Control	II-IV	2006	January 2008
South Dakota*	Board of Pharmacy	II-IV	2010	
Tennessee	Board of Pharmacy	II-V	2003	December 2006
Texas	Department of Public Safety	II	1982	July 1982
Utah	Board of Pharmacy	II-V	1995	January 1997
Vermont	Department of Health	II-IV	2006	January 2009
Virginia	Board of Pharmacy	II-IV	2002	September 2003-pilot program in southwest Virginia; June 2006 statewide prescription monitoring
Washington* **	Department of Health	II-V	2007	
West Virginia	Board of Pharmacy	II-IV	1995	1996 schedule II only; January 1 2003
Wisconsin*	Board of Pharmacy	II-III	2010	
Wyoming	Board of Pharmacy	II-IV	2004	July 2004

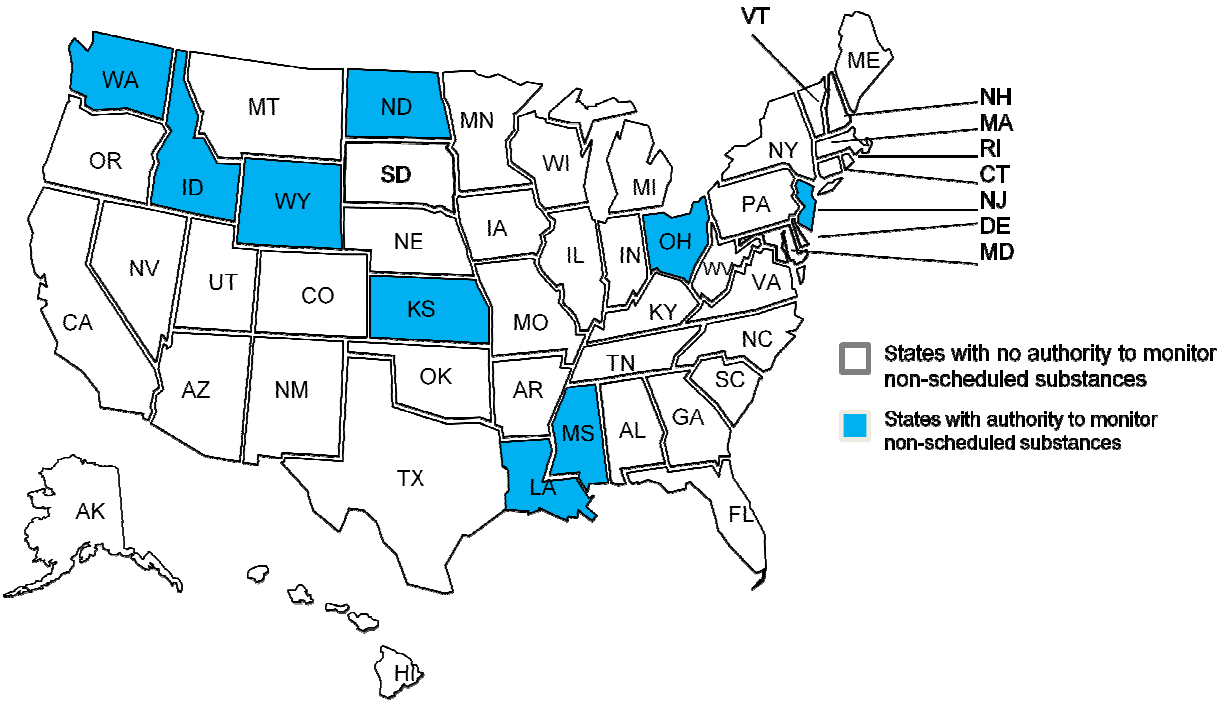
* States with legislation in place for establishment of PDMP, but not yet implemented.

** Nevada's law mandated that both the Board of Pharmacy and the Investigation Division of the Department of Public Safety cooperatively establish the state's PDMP; however, the Board of Pharmacy carries most of the responsibility with regard to its administration.

***Washington has temporarily suspended its PMP operations due to budgetary constraints. A bill was proposed during the most recent legislative session that would have allowed for the statewide operation of a privately funded PMP; however, the bill did not pass, and the Washington Legislature is no longer in session.

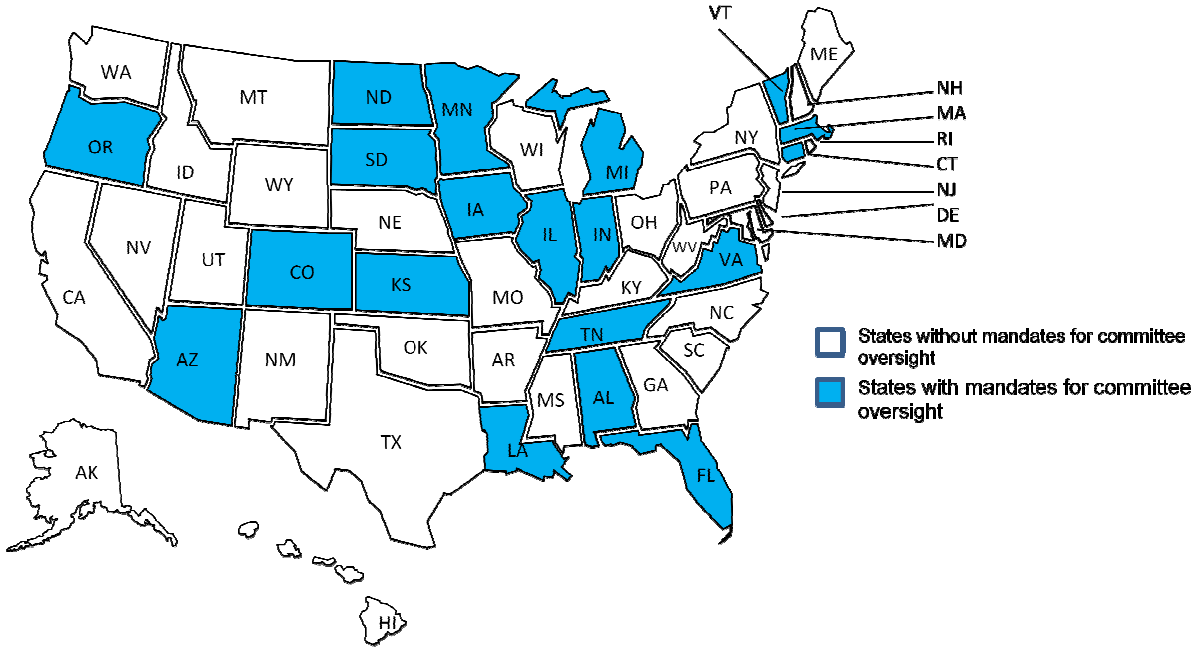
In addition to the general schedules outlined in Table 1, some states also include other more specific guidelines for substance monitoring within their PDMP. For example, Iowa monitors schedule III and IV substances that the advisory council and Board of Pharmacy determine to be addictive or fatal if not taken under the care of a licensed practitioner, and Oklahoma's PDMP statute excludes from monitoring schedule V substances containing any detectable quantity of pseudoephedrine (3). Nine states have PDMP laws that allow monitoring of non-controlled or nonscheduled substances under specific circumstances. It should be noted that not all states with statutory authority to monitor non-controlled substances are currently monitoring for such substances and, in fact, additional regulations may be needed before monitoring can commence in some states. (Figure 2) (2, 12).

Figure 2. States with Statutory Authority to Monitor Non-Controlled Substances



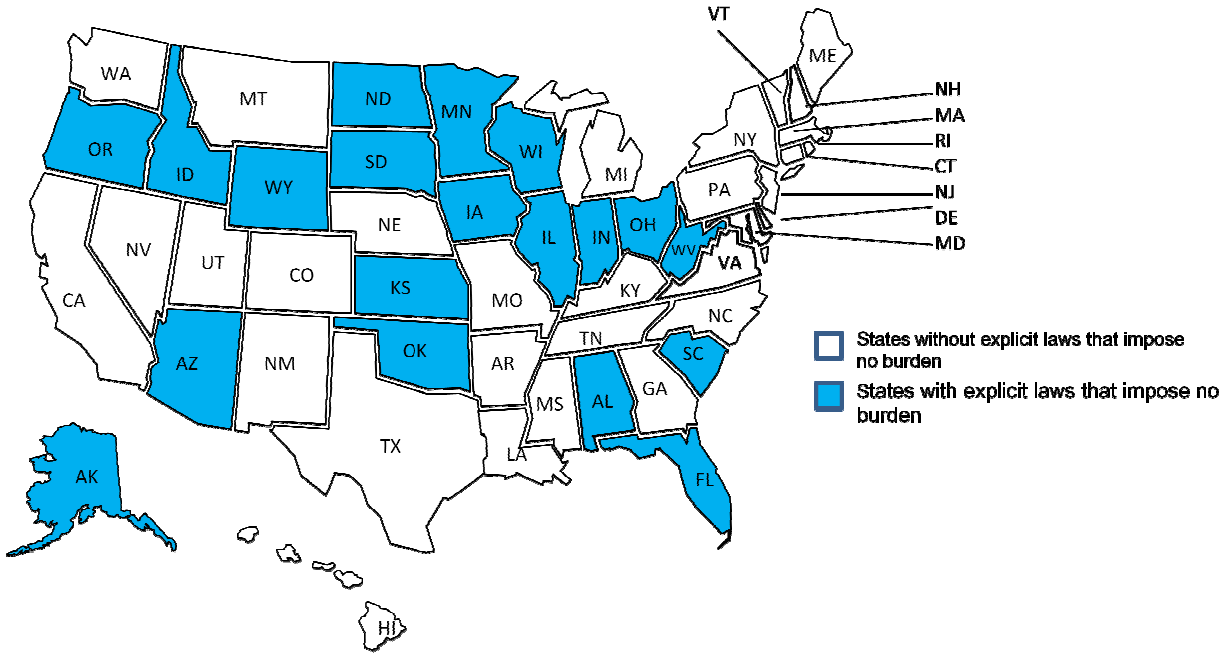
Some states statutorily mandate that their PDMP work with or use an advisory committee, council, task force, or working group during program implementation, monitoring and evaluation. The states with such mandates are depicted in Figure 3 (12).

Figure 3. States with Statutory Requirements for Committee Oversight of Prescription Drug Monitoring Program Operations



Of the 33 states that have operational PDMPs, 19 have laws that impose no expectation on practitioners to access the PDMP information prior to prescribing or dispensing controlled substances (Figure 4) (12). By outlining this explicitly in the law, practitioners are provided immunity from civil liability for accessing, or failing to access, prescription information contained in the PDMP database. These laws govern dispensers practicing in those states as well, with the exception of Iowa and Indiana. Nevada, on the other hand, mandates that under certain circumstances the practitioner must review information contained in the PDMP database for the prior 12 months before prescribing or dispensing a controlled substance to determine whether the prescription is medically warranted (2).

Figure 4. States with Explicit Laws that Impose No Expectation on Practitioners to Access Program Data Prior to Prescribing or Dispensing



Cost of Prescription Drug Monitoring Program Operation

The cost of implementing and operating a PDMP varies from state to state. Average cost for implementation of a PDMP is approximately $350,000 while annual operating costs have been estimated to range from $100,000-$1million (9).

Many factors contribute to the wide variation in the annual operating costs of a PDMP. An analysis of PDMPs conducted by the U.S. Government Accountability Office (13) identified the following as major factors that impact program operational costs:

1. Size of the state
2. Differences in the PDMP implemented
    a. Number of schedules monitored/drugs covered; some states in addition to monitoring scheduled drugs, also monitor non-scheduled drugs with potential for abuse
    b. Method for collecting prescription information

c. The way in which the prescription information is used - some states use their PDMP proactively, while others use it reactively; proactive use requires more resources and thus incurs additional cost
d. The type of state agency housing the PDMP
e. Method of analyzing the data

3. Number of pharmacies reporting prescription information to the PDMP
4. Number of providers and law enforcement agencies requesting prescription information
5. Number of staff required to ensure smooth operation of the PDMP
6. Number and type of outside contractors required to run the PDMP

Transmission of Prescription Drug Monitoring Program Data

The transmission of prescription information (patient identifier, drug dispensed, date of dispensing, quantity dispensed, prescriber, and dispenser) from dispensers to the PDMP administrator is a multi-step process. Most states with active PDMPs have employed external vendors to collect prescription information from pharmacies, the primary dispensers of controlled substances. The data is verified and checked for errors then transmitted to the PDMP. Some state PDMPs have mechanisms that allow providers who dispense controlled substances infrequently to submit information via paper format, or via secure websites that allow data entry for a single dispensing transaction.

The data is checked for errors at many different levels. For example, in Kentucky when data is transmitted to the authorized vendor, it is automatically scanned for errors such as missing patient identifier or incomplete prescription information. When this process is complete, the data is automatically uploaded into the PDMP system, which again checks for errors. Only after the data has undergone this sequence of checks is it made available to registered users.

At this time, no state has implemented a program that requires real-time data transmission at the point of controlled substance dispensing. Currently, the most common time frame for data transmission is bi-weekly. The state of Oklahoma, however, is hoping to reach real-time data transmission by the year 2011.

Confidentiality of Prescription Drug Monitoring Program Data

Prescription drug monitoring programs collect and house sensitive, patient-specific information that is governed under the Health Insurance Portability and Accountability Act (HIPAA). To safeguard patient information, there are numerous security measures that come into play, with checks and balances taking place at multiple levels. First of all, there is the physical security.

The PDMP is physically in a place with limited access, where only a select few authorized personnel are allowed to enter. Hardware and software encryption, to prevent encoding of information should any breech in security occur, is also a standard feature of PDMPs. In addition, there is a rigorous registration process for authenticating users. Prior to granting access, practitioners' DEA numbers are checked and verified and their standing with the respective licensing board is investigated. After access is granted, there are other security measures in place to help protect patient information. An audit trail is created for every user that records when and where the data were accessed, the frequency of access, and for which patients. There are checks in place that "time-out" a user if the system is left idle. Some programs also deny access to users if they have not accessed the system in a specified number of days. These and many other security measures are employed to help securely maintain the database and protect patient information.

Since the inception of PDMPs in the 1930's, there have been no reports of confidentiality breeches until very recently. On April 30th 2009, the Virginia Department of Health Professions was informed that their PDMP database was accessed by an unauthorized user. Currently an ongoing investigation of this incident is being conducted by both federal and state law enforcement agencies (14). Patients whose prescription record contained Social Security numbers were contacted via email to explain the potential breech in information, and were cautioned to pay particular attention to activities involving their Social Security numbers over the next year (14).

Accessibility and Currency of Prescription Drug Monitoring Program Reports

Access to PDMP reports varies by state (15). Some states only allow law enforcement agencies involved in drug-related investigations and regulatory boards to access the information. In other states, a variety of groups are authorized to access the prescription information, including prescribers and pharmacists who use the information at point-of-care to make prescribing and dispensing decisions.

For most states the PDMP is electronic and available online. Authorized users have direct access to the online system, and when requested, a report is generated within seconds to minutes. Some states, such as Michigan, North Dakota, and Utah, also accept requests via fax. This process takes a bit longer, generally one to two days, as requester information must be authenticated. In other states, a report may take as long as 14 days.

As discussed previously, the time frame in which prescription data is transmitted to PDMPs also varies from state to state. For the vast majority of states, dispensers are required to report prescription data to the PDMP system every 7-14 days. Therefore, when a prescriber or dispenser requests a report on a patient, the information in the report may be up to 14 days

old. Many state PDMPs are moving toward requiring more frequent transmission of prescription information in hope of increasing the currency of information to improve reporting. Table 2, compiled from a variety of sources, provides a summary of groups authorized to access PDMP reports by state, the process by which the reports are accessed and the currency of the reports (3, 7, 15 -16).

Table 2. Accessibility and Currency of Prescription Drug Monitoring Program Reports by State

State	Groups Authorized to Access	Mechanism of Access	Currency of Reports
Alabama	•Licensed practitioners approved to prescribe, dispense, or administer controlled substances •Licensed physician assistants who are authorized to prescribe •Licensing boards •Law enforcement agencies •Employees of the department and consultants engaged by the department for operational and review purposes	•Physician and pharmacists-online within seconds •Law enforcement – requires affidavit and may take up to 14 days	•Data uploaded bi-weekly •Lag time of 7-14 days
Alaska	•Licensing boards •Licensed practitioners •Licensed or registered pharmacists •Federal, state, and local law enforcement authorities •Authorized board personnel or contractors as required for operational and review purposes •Individual for whom data was entered into the database may request a report; individual does not have direct access to data information	Program not yet implemented	Program not yet implemented
Arizona	•Person authorized to prescribe or dispense controlled substances •Individual requesting his/her own prescription information-individual does not have direct access to data information •Professional licensing boards •Local, state, or federal law enforcement or criminal justice agency •Arizona Health Care Cost Containment System administration regarding individuals who are receiving services •Person serving a lawful order of a court of competent jurisdiction •Board staff for purposes of administration and enforcement	•Physician and pharmacists-online within minutes •Law enforcements and regulatory boards- require notarized affidavit and report can take up to 2-3 days	
California	•Licensed practitioner eligible to prescribe Schedule II,III, and IV drugs •Pharmacists	•Manual via fax or US mail •Near future plans for 24 hour online access to registered users	
Colorado	•Licensed practitioner with authority to prescribe controlled substances •Practitioners engaged in a legitimate program to monitor a patient's controlled substance abuse •Licensed pharmacist •Law enforcement involved in a bona fide investigation •Board staff responsible for administering the program •Individual who is the recipient of a controlled substance prescription may request a report-does not have direct access to database •State Board of Pharmacy may release information to persons	•Pharmacists and physicians-online within seconds	

	for the purpose of bona fide research or education •The board may share information with out-of-state health care practitioners		
Connecticut	•Practitioners and pharmacists for the purpose of patient care •Practitioners for the purpose of education in lieu of disciplinary, civil, or criminal action •Regulatory, investigative, or law enforcement agencies for disciplinary, civil, or criminal purposes •Public or private entities for statistical, research, or educational purposes provided that the patients' confidentiality is not compromised	•Pharmacists and physicians-online within seconds	•Data uploaded bi-weekly •Potential lag time of 14 days
Florida	•Prescriber, pharmacist, or dispenser •Department or its regulatory boards responsible for licensure, regulation, or discipline of practitioners, pharmacists •Attorney General for Medicaid fraud cases (no direct access) •Patient or legal guardian, or designated health care surrogate may request a report- individual does not have direct access to database •Law enforcement agency during active investigations •Department staff for the purpose of calculating performance measures (no direct access) •Program implementation and oversight task force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives	Program not yet implemented	Program not yet implemented
Hawaii	•Registrant authorized to administer, prescribe, or dispense controlled substances •Pharmacists •Law enforcement officers, investigative agents, federal, state, or county law enforcement agencies, prosecuting attorneys, or the Attorney General •Other state-authorized governmental prescription-monitoring programs		
Idaho	•Practitioner with a license to prescribe controlled substances •Licensed pharmacist • Patient or legal guardian, or designated health care surrogate may request a report-individual does not have direct access to database •Upon the lawful order of a court of competent jurisdiction •Prosecuting attorneys, deputy prosecuting attorneys, and special prosecutors of a county or city and special assistant attorney general from the Office of the Attorney General engaged in enforcing laws regulating controlled substances •Licensing boards •Peace officers employed by federal, state, and local law enforcement agencies •Authorized individuals under the direction of the Department of Health and Welfare for the purpose of monitoring and enforcing that Department's responsibilities under the public health, Medicare, and Medicaid laws	•Registered users-instantly online •Fax requests within 24 hours	
Illinois	•Licensing boards engaged in an investigation •Investigator for the Consumer Protection Division of the Office of the Attorney General, a prosecuting attorney, the Attorney General, a Deputy Attorney General, or an investigator from the Office of the Attorney General who is engaged in an investigation or an adjudication •Law enforcement officer engaged in an investigation •Prescription monitoring entities in other states	•Pharmacists and physicians-online within 10 seconds	
Indiana	•Licensing boards engaged in an investigation •Investigator for the Consumer Protection Division of the Office		•Data uploaded weekly

	of the Attorney General, a prosecuting attorney, the Attorney General, a Deputy Attorney General, or an investigator from the Office of the Attorney General who is engaged in an investigation, an adjudication, or prosecution •Law enforcement officer •Practitioner or practitioner's agent certified to receive information from the program •Controlled substance monitoring program in another state with which Indiana has established an interoperability agreement		•Lag time of 7 days
Iowa	•Prescribing practitioner •Pharmacist •Individual who requests his/her own prescription information-individual does not have direct access to the database •Pursuant to a court order or subpoena for an investigation •Professional licensing boards and regulatory agencies •Law enforcement agencies •Private entities for statistical, research or educational purposes	•Automatically processed reports-available to users within seconds •If staff intervention needed to process the request-available within 24 hours or following a weekend	•Data uploaded bi-weekly •Pharmacies may chose to report more frequently such as weekly or daily
Kansas	•Persons authorized to prescribe or dispense scheduled drugs or drugs of concern •Individual requesting his/her own prescription information-individual does not have direct access to database •Professional licensing, certification, or regulatory boards •Local, state, and federal law enforcement or prosecutorial officials engaged in an investigation •Persons authorized by a grand jury subpoena, inquisition subpoena, or court order •Personnel of the prescription monitoring program advisory committee for the purpose of operation of the program	Program not yet implemented	Program not yet implemented
Kentucky	•Practitioner or pharmacist •Licensing boards •Grand jury subpoena •Department for Medicaid Services •Judge or probation officer administering a diversion or probation program •Certified Kentucky Peace Officer	•Pharmacists and physicians-online within 5-15 minutes	•Data uploaded once every 7 days •Potential lag time of days
Louisiana	•Persons authorized to prescribe or dispense controlled substances •Professional licensing boards •Designated representatives from the Louisiana Medicaid program •Designated representatives of the board and any vendor or contractor establishing or maintaining the prescription monitoring program •Local, state, and federal law enforcement agencies •Grand jury subpoena, court order, or court-ordered warrant •Individual requesting his/her own prescription information-individual does not have direct access to the database •Program personnel for the purpose of responding to legitimate inquiries from authorized users of other individuals	•Pharmacists and physicians-online within 10-45 seconds •Law enforcement with subpoena-within 24 hours	
Maine	•Prescriber •Dispenser •Professional licensing boards •Individual requesting his/her own prescription information-individual does not have direct access to database •Office personnel or personnel of any vendor or contractor as necessary for establishing and maintaining the program's	•Pharmacists and physician-online within seconds •Licensing boards and law enforcement submit form requests-within 24-	•Data uploaded bi-weekly Lag time of 14 days •Plans for weekly submission to decrease lag time to 7 days

	electronic system •Office that administers the MaineCare program • Office of the Chief Medical Examiner for the purpose of conducting an investigation or inquiry	48 hours	
Massachusetts	•Professional licensing boards •Law enforcement agency when conducting a bona fide investigation •Executive Office of Health and Human Services for the purpose of identifying suspected fraud or abuse of the Mass Health program •Practitioner or pharmacist •Individual requesting his/her own prescription information-individual does not have direct access to database	•No current online system •If no approval needed by the medical review group-1-3 days •If approval needed by medical review group-up to 3 weeks	•Lag time of 14-28 days
Michigan	•Professional licensing board •Practitioner or pharmacist •State operated Medicaid program •Employee or agent of the department •State, federal, or municipal employee or agent whose duty is to enforce the laws of the state or the United States relating to drugs •Court order •Officials for a drug related criminal investigation	•Pharmacists and physicians-online within minutes •Fax requests within 1-2 days	•Data uploaded bi-weekly •Lag time of 14 days
Minnesota	•Pharmacists and practitioners •Individual requesting his/her own prescription information-individual does not have direct access to the database •Professional licensing boards •Personnel of the board engaged in the collection of controlled substance prescription information •Authorized personnel or vendor under contract with the board who are engaged in the design, implementation, or operation, and maintenance of the electronic reporting system •Federal, state, and local law enforcement authorities involved in an investigation •Personnel of the Medicaid assistance program	Program not yet implemented	Program not yet implemented
Mississippi	•Pharmacists and practitioners •Federal and state law enforcement agencies •Professional licensing boards	•If request is screened, average response time is 2 hours	
Nevada	•Practitioners authorized to write prescriptions •Upon the lawful order of a court of competent jurisdiction •Individual requesting his/her own prescription information-individual does not have direct access to the database •Board and Division to identify any suspected fraudulent or illegal activity related to the dispensing of controlled substances	•Pharmacists and physicians-online within seconds	
New Jersey	•Practitioner authorized to prescribe controlled substances •Pharmacist authorized to dispense controlled substances •Professional licensing boards •State, federal, or municipal law enforcement officer involved in an investigation •Designated representative of a state Medicaid program who certify that they are engaged in a bona fide investigation of a designated practitioner or patient •Grand jury subpoena •Authorized personnel of the division or vendor or contractor responsible for establishing and maintaining the program PDMPs of other states with which the Division has established an interoperability agreement	Program not yet implemented	Program not yet implemented
New Mexico	•Persons authorized to prescribe or dispense controlled substances	•System is manual •Requests take 5	

	•Individual requesting his/her own prescription information-individual does not have direct access to the database •Professional licensing boards •Professional licensing authorities of other states if their licensees practice in the state Local, state, and federal law enforcement or prosecutorial officials engaged in an ongoing investigation •Human Services Department regarding Medicaid program recipients •Metropolitan, district, state, or federal court under grand jury subpoena or criminal court order •Personnel of the board for purposes of administration	minutes-1 hour to be returned •Federal grant applied for and may have an online system within 1-2 years	
*New York	•Practitioners to notify him/her that a person under his/her treatment with a controlled substance prescription may also have a controlled substance prescription from another practitioner •Professional licensing boards	•Currently developing an online practitioner notification program	
North Carolina	•Persons authorized to prescribe or dispense controlled substances •Individual who requests his/her own prescription information-individual does not have direct access to the database •Special Agents of the North Carolina Bureau of Investigations who are involved in an ongoing investigation •Primary monitoring authorities for other states involved in an ongoing investigation •Court pursuant to a lawful court order in a criminal action •Division of Medical Assistance for purposes of administering the State Medical Assistance Plan •Professional licensing boards	•Pharmacists and physicians-online within seconds	•Data entered bi-weekly •Lag time of 14 days
North Dakota	•Practitioners and pharmacists •Individual who requests his/her own prescription information-individual does not have direct access to the database •Professional licensing boards •Local, state, and federal law enforcement or prosecutorial official engaged in an investigation •Department of Human Services for purposes regarding the utilization of controlled substances by a Medicaid recipient •Workforce safety and insurance for purposes regarding the utilization of controlled substances by a claimant •Judicial authorities under grand jury subpoena or court order •Public or private entities for statistical, research, or educational purposes •Professional peer review committee	•Pharmacists and physicians-online within seconds •Fax requests-24 hour window to return requests-most returned within a few hours	•Data entered weekly •Data entered can occasionally take up to 1 week to show up in the system •Potential lag time of 7-14 days
Ohio	•Practitioners or pharmacists •Federal, state, or local law enforcement officer involved in an investigation •Professional licensing boards •Pursuant to a subpoena issued by a grand jury •Individual requesting his/her own prescription information-individual does not have direct access to the database	•Pharmacists and physicians-online within 11 seconds	•As of September 1, 2009, all pharmacists must report weekly (previously reported bi-weekly) •Potential lag time 7-14 days
Oklahoma	•Peace Officers who are employed as investigative agents of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control •United States Drug Enforcement Administration group supervisor •Professional licensing boards •Pursuant to a grand jury subpoena	•Pharmacists and physicians-online within a few seconds	
Oregon	•Practitioners and pharmacists •Professional licensing boards	Program not yet implemented	Program not yet implemented

	•Pursuant to a valid court order •Law enforcement agencies •Designated representatives of the Department or any vendor or contractor with whom the Department has contracted to establish or maintain the electronic system of the PDMP •PDMP of other states •Public or private entities for educational, research, or public health purposes •Officials of the Department who are conducting special epidemiologic morbidity and mortality studies • Individual requesting his/her own prescription information-individual does not have direct access to the database		
Pennsylvania	•The criminal justice agency •Every dispensing practitioner		•Data entered once monthly
Rhode Island	•Regulatory, investigative, or law enforcement agencies for disciplinary, civil, or criminal purposes •Public or private entities for statistical research, or educational purposes		
South Carolina	•Practitioners or pharmacists •Individual who requests his/her own prescription information-individual does not have direct access to the database •Professional licensing boards •Local, state, or federal law enforcement or prosecutorial official engaged in an investigation •South Carolina Department of Health and Human Services regarding Medicaid program recipients •Properly convened grand jury pursuant to a subpoena •Qualified personnel for the purpose of bona fide research or education	•Approved direct user-online within seconds •Other users submit request-report usually within 24-72 hours	
South Dakota	•Licensed health care practitioners •Licensed pharmacists •Professional licensing boards •Any individual who requests prescription information of the individual or the individual's minor child •Local, state and federal law enforcement or prosecutorial official engaged in an investigation •Any judicial authority under grand jury subpoena or court order for investigative purposes •Any public or private entity for statistical, research, or educational purposes after the information is de-identified •Any insurer for purposes regarding utilization of controlled substances by claimant •Any committee of a health care organization for purposes of peer review • Department of Social Services regarding Medicaid program recipients	Program not yet implemented	Program not yet implemented
Tennessee	•Licensed health care practitioners •Licensed pharmacists •Authorized committee, board, or department of health personnel engaged in analysis of controlled substances prescription information •Personnel of the committee specifically assigned to conduct analysis or research •Office of the Inspector General, Medicaid Fraud Control Unit, Tennessee Bureau of Investigations, and Bureau of TennCare's Chief Medical Officer, Associate Chief Medical Directors, Director of Quality Oversight, and Associate Director of Pharmacy actively engaged in analysis of controlled substances prescription information	•Information available to users within seconds	•Data entered bi-weekly •Potential lag time of 7-21 days (Takes about 1 week for the data to be collected and uploaded into the database)

	•Patient for whom the information relates to for purposes of treatment adjustment or counseling may request a report-patient does not have direct access to the database •District Attorney General for purposes of investigation		
Texas	•Practitioner or pharmacist who are inquiring about a recent Schedule II, III, IV or V prescription history of a patient •Pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity •Law enforcement or prosecutorial official engaged in an investigation •Professional licensing boards •Authorized officer or member of the Department engaged in administration, investigation, or enforcement of this chapter or another law governing illicit drugs in the state		
Utah	•Licensed practitioners and licensed pharmacists •Employee of the practitioner designated to access the prescription information on behalf of the practitioner •Federal, local, and state law enforcement authorities •Mental health therapist if the information relates to a patient enrolled in a licensed substance abuse program and receiving treatment from or under the direction of the mental health therapist •Authorized Division personnel engaged in analysis of controlled substance prescription information, or who is assigned to conduct investigations related to controlled substance laws •Employees of the Department of Health assigned to conduct scientific studies regarding the use or abuse of controlled substances	•Pharmacists and physicians-online within seconds •Fax requests-within 15 minutes	•Data entered weekly •Lag time of 1-7 days
Vermont	•Practitioners or pharmacists •Professional licensing boards involved in a bona fide investigation •Patient for whom a prescription is written may request a report-patient does not have direct access to the database •The commissioner of public safety •Personnel or contractors as necessary for establishing and maintaining the Vermont PDMS		
Virginia	•Practitioners or pharmacists •Professional licensing boards •Grand jury subpoena •Personnel involved in Medicaid fraud investigation •Designated employees of the Office of the Chief Medical Examiner for information relevant to the determination of the cause of death of a specific recipient •Personnel involved in a bona fide research, or education	•Pharmacists and physicians- online within seconds	•Data entered bi-weekly (required) •Some pharmacists enter weekly
Washington	•Pharmacists and practitioners •Professional licensing boards •Federal, state, and local law enforcement agencies •Authorized practitioners of the Department of Social and Health Services regarding Medicaid program recipients •Director or Director's designee within the Department of Labor and Industries regarding workers' compensation claimants •Entities under grand jury subpoena or court order	Program not yet implemented	Program not yet implemented
West Virginia	•Pharmacists and practitioners •Professional licensing boards •Authorized agents of the Federal Drug Enforcement Administration •Members of the West Virginia State Police expressly authorized by the superintendent of the West Virginia State Police	Program not yet implemented	Program not yet implemented

	•Inspectors and agents of the board		
Wisconsin	•To be determined	Program not yet implemented	Program not yet implemented
Wyoming	•Pharmacists and practitioners •Law enforcement agencies •Individual requesting his/her own information or if the patient is a minor, to his/her parents or guardian-individual does not have direct access to the database •Practitioners, pharmacists and pharmacies for educational, research, or public information purposes	•No online access to users •Requests by users returned within one hour on most occasions	

*In New York, only licensed practitioners who are registered with the US DEA are authorized to view the data, and only for the purpose of making treatment decisions. The Department of Health is currently seeking a change in law which would allow solicited disclosure of patient information to pharmacists.

Types of Prescription Drug Monitoring Program Reports

In some states, the PDMP is "reactive" meaning that only solicited reports are generated in response to a query by authorized users such as prescribers, dispensers and other groups with the appropriate authority. On the other hand, PDMPs of other states are "proactive", generating unsolicited reports when there is reason to suspect that violations on the part of patients or users have occurred (17).

Processes for providing unsolicited reports vary among states. Some states have thresholds that must be reached for an unsolicited report to be generated. For example, in New York, if a patient has received controlled substance prescriptions from two or more pharmacies during the previous calendar month, a report will be automatically generated and provided to prescribers. In North Dakota, an unsolicited report is sent to pharmacies and practitioners when a patient utilizes 15 or more practitioners, or eight or more pharmacies in one year.

States' Evaluation of Prescription Drug Monitoring Programs

Although many states have not conducted a formal evaluation of their PDMP, there is a general consensus that PDMPs are effective in reducing abuse and diversion of pharmaceutical controlled substances (16).

<u>Maine</u>

The state of Maine is one of the few states that has conducted an in-depth evaluation of its PDMP. This evaluation, completed in March 2007 by researchers at the Muskie School of Public Service at the University of Southern Maine, was done in an effort to answer several questions related to PDMP implementation, use, impact on patient care, collateral and/or unintended or adverse consequences and impact on abuse rates in Maine.

In order to evaluate the Maine PDMP, surveys were conducted of prescribers who were registered users of the Maine PDMP and dispensers who enter data into the Maine PDMP system. Additionally, interviews with members of the PDMP advisory committee, Office of

Substance Abuse (OSA) staff, clinical advisory committees and heads of professional licensing boards were conducted. Secondary data analyses of queries from the PDMP database, special reports, and trends from the public use data-base were performed.

Survey results revealed that since clinicians have started registering for the program in January 2005, the program has grown steadily, with over 1000 prescribers registering by October 2006. The most popular specialties registering for the program were family medicine, mid-level practitioners such as advanced registered nurse practitioners, internists, psychiatrists and emergency medicine specialists. Data analysis showed that prescribers have successfully used the program to identify 'doctor shopping'. The researchers found that the integrity of the program and patient confidentiality were maintained. As a result of proper and efficient use of the program, patients who were addicted got the necessary treatment and those who needed stronger prescriptions received them. The evaluation suggested that there was not a "chilling effect", meaning that increased regulation through PDMP did not cause prescribers to prescribe fewer controlled substances than were needed clinically (18).

Virginia

In May 2004, the American Cancer Society (ACS) and the South Atlantic Chapter of the ACS, in collaboration with the Virginia Cancer Pain Initiative, contracted with the Survey and Evaluation Research Laboratory (SERL) at the Virginia Commonwealth University to conduct an evaluation on the usefulness and effectiveness of Virginia's PDMP. Surveys were distributed to all physicians in State Health Planning Region III in Southwest Virginia. At the time of the survey, only Schedule II drugs were being monitored.

Results from the survey indicated that after two years of PDMP operation, 48% of physicians were aware of the existence of the PDMP prior to receiving the survey. Survey data also revealed that approximately one-third (36%) of physicians reported that over the past three years they had prescribed fewer Schedule II prescription drugs, citing increased media coverage and law enforcement activity as the main reasons. Of those physicians reporting decreased Scheduled II prescribing, over half (60%) indicated this change in prescribing had not impacted their ability to manage their patients' pain while 31% percent indicated a negative impact on their ability to manage their patients' pain. Fifty-seven percent of those who had decreased their prescribing of Schedule II medications report that as a result they had been prescribing more Scheduled III and IV medications.

At the time this evaluation was conducted, written consent from patients was required prior to gaining access to PDMP reports. Once consent was given, the physician submitted a written request to the Virginia Department of Health Professions. Only 11% of physicians stated that they had submitted a query for patient information. For the remaining physicians, when asked

why no requests for information were submitted, most (40%) were unaware of this aspect of the program while others viewed reports as unnecessary (25%) or did not request because reports were not received immediately (reports received within 1-7 days) (18%). Nine percent did not access reports because they were unable to gain consent from patients. Regardless of the very low utilization of the PDMP reports, 68% of physicians reported that the PDMP is useful for monitoring their patients' prescription history and decreasing the incidence of 'doctor shopping' (19).

Kentucky

In 1998, the Commonwealth of Kentucky enacted its PDMP – the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system. To assess the program's impact on abuse, misuse, and diversion of pharmaceutical controlled substances in Kentucky, the Cabinet for Health and Family Services, Office of Inspector General, the administrative agency responsible for KASPER, conducted an internal evaluation of the program via a satisfaction survey distributed to KASPER users in 2004.

To facilitate data collection and proper sampling, the investigators divided the state into six regions and a systematic sample was selected from each region. Surveys were sent to both providers (i.e. prescribers and dispensers with KASPER accounts) and requesters (i.e. prescribers and dispensers who had actually made a request for a KASPER report). Only responses from the requester respondent group were used in the analysis. There was a 67.7% response rate from the requester group (20).

Results indicated a high usage rate of the PDMP among the various user groups and suggest that as more physicians and pharmacists become aware of KASPER, an increase in the usage of KASPER is likely. There was a general consensus among respondents that the KASPER system is an effective tool to assist in patient management, although some expressed concern over the quality and timeliness of the data. With regard to efficiency of the system, results indicated that the system was user-friendly, requiring minimal training; however, there was a need for improvement of the overall system in regards to the timeliness of reports. To accomplish this goal, the Commonwealth of Kentucky with the aid of a Harold Rogers Program Grant, upgraded its system from manual to web-based, with the implementation of eKASPER, Kentucky's enhanced KASPER system, in 2005.

One year after the implementation of eKASPER, Kentucky conducted another survey to evaluate user satisfaction with the new system, and to assess whether there had been any change in the level of satisfaction from the 2004 survey (21, 22). For this evaluation, the Commonwealth of Kentucky was again divided into 6 study regions, with separate response

sections for prescribers, dispensers, and law enforcement. The response rate for this survey was 66.8%, quite similar to the 67.7% received in 2004.

Results revealed an increase of 13.8 % in user satisfaction compared to 2004, and an overall 12.5% increase in the opinion that KASPER is an effective tracking tool. Among the various respondent groups, there was a 16.6% increase in the belief that KASPER is a very useful and efficient tool for tracking patients' prescription drug history. With regard to 'doctor shopping', there was a 10.3% increase from 2004 among those responding that KASPER is an effective tool for identifying 'doctor shopping'.

Additionally, analysis revealed a three-fold increase in the use of KASPER in the clinical setting as a means to identify individuals with substance abuse problems. Approximately 75% of law enforcement officers surveyed reported that KASPER is a very efficient tool for obtaining evidence in an investigation.

It is important to note that while the population in Kentucky has remained relatively constant, there has been an average increase of 3% per year in the number of controlled substance prescriptions issued by Kentucky prescribers. Most interestingly, in the period of implementation of eKASPER, 2005-2006, there was an even bigger jump, 6%, in the number of controlled substance prescriptions generated. Thus, implementation of KASPER does not appear to be having a chilling effect.

In summary, the results from both the 2004 and 2006 satisfaction surveys suggest the majority of users consider KASPER to be a very useful and efficient tool for detecting abuse and diversion. It is efficient at tracking patients' prescription record, and law enforcement agents regard it as an extremely useful tool to obtain information in an investigation (20).

Impact of Prescription Drug Monitoring Programs on Access to Care

As part of its research during the design and passage of the National All Schedule Prescription Electronic Reporting Act (NASPER), the Department of Health and Human Services conducted an evaluation to review whether PDMPs have had a negative impact on patient access to treatment. Special focus was placed on the pediatric population, enrollment of patients in clinical trials and research, and patients requiring treatment for pain or addiction (23).

This evaluation was conducted at a time when PDMPs were undergoing changes such as conversion to electronic form, sharing of data among physicians and other practitioners, implementation of web-based portals for practitioner access, and elimination of serialized prescriptions for select controlled substances in all but one state. As a result of these changes, the evaluation was not able to reach a solid conclusion as to whether PDMPs have had a

negative impact on patient access to care. However, the data revealed information that was viewed by the evaluators as helpful in possibly providing ways to improve the structure of PDMPs (23).

Data for this analysis was obtained from 11 states possessing a PDMP and analysis suggested that the older, multiple-copy prescription form programs may have had a negative impact on patients' access to treatment. This was seen most distinctly in patients requiring opioids for pain management. This result was consistently found across literature review, data analysis, and key informant responses, and was most noted in states where special prescription forms were used, and where Schedule II, but not Schedule III medications, were being monitored. Furthermore, in states with PDMPs, patients were slightly more likely to use at least one Schedule III opioid analgesic per year than those living in states without a PDMP. This may represent a "substitution effect", where prescribers switch from prescribing a Schedule II product whose dispensing is tracked by the PDMP, to one for which reporting is not required. (23).

With regard to addiction and access to opioid agonist therapies for treatment, results were not consistent across literature review, data analysis, and key informant responses. Automation of Reports and Consolidated Orders Systems (ARCOS) provided evidence that suggests having a PDMP may have a negative effect on the use of methadone to treat addiction; however, no definitive conclusion could be reached (23).

While a previous study had reported a negative impact on the pediatric population relative to the treatment of pain, the study conducted by the Department of Health and Human Services (DHHS) did not reveal any conclusive evidence that PDMPs have had a negative effect on pediatric patients' access to care. One of the obstacles encountered in the DHHS evaluation was the inability to isolate the pediatric population and the drugs prescribed for them. The consensus was that additional research is needed to fully evaluate this issue.

In conclusion, based on the evaluation conducted by the Department of Health and Human Services, no clear consensus can be reached on whether PDMPs have an adverse effect on patients' access to pharmacologic treatment.

Future Plans for State Prescription Drug Monitoring Programs

Among the various states utilizing a PDMP, many report the desire to update their PDMP toward a "real-time" system. In the strictest sense of the term, real time means automatic prescription data transmission at the point of dispensing, although some states view real-time as once daily reporting. Real-time data transmission would significantly improve the currency

of the PDMP reports and provide more accurate information at the point of care for use in treatment decisions. Several states, including Kentucky, are planning studies to identify barriers and resources needed to implement real-time data transmission.

As PDMP programs have been implemented in states, patients who 'doctor shop' often cross state lines to obtain and fill prescriptions. Thus, interstate sharing of PDMP program data will become increasingly important to the success of PDMP programs in reducing abuse, misuse and diversion of controlled substance medications.

Conclusion

Many states have implemented prescription drug monitoring programs to assist in detecting and preventing abuse, misuse, and diversion of controlled substances. While evidence suggests that individual state programs may be effective, more data are needed to document the true impact of PDMPs. Additionally, based on available data at this time, PDMPs do not appear to be causing a chilling effect, although an objective analysis of the potential for this is needed. In realizing this need, the authors of the report, under contract with the Kentucky Cabinet for Health and Family Services, Office of the Inspector General, are conducting an independent evaluation of the impact and effectiveness of the Kentucky All Schedule Prescription Electronic Reporting program.

States continue to search for new methods to enhance the capabilities of existing PMPs. Although real-time data transmission has not been implemented in any program to date, several states are exploring this option. Interstate sharing of data is also an area that is of interest to a number of states.

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